



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,794	08/03/2001	Christoph Wagener	4121-124	9609

23448 7590 12/05/2003

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,794	Applicant(s) WAGENER ET AL.	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1, 4, and 6 have been amended.
Claims 8-10 have been added.
Claims 3-4 have been canceled.
2. Claims 5, 7, 9 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made in Paper No. 7.
3. Claims 1 2, 6, and 8 are under examination.
4. It is acknowledged that the method claims 9-10 will be rejoined upon allowance of the composition claims under MPEP 821.04.
5. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
6. The following Office Action contains NEW GROUNDS of rejection.

Claim Objection

7. Claim 6 is objected to as depending on a canceled claim. The claim is being interpreted as depending on claim 1.

Rejections Withdrawn

8. The rejection of claims 1 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

9. The rejection of claims 1-2 and 6 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

10. The rejection of claims 1-2, 6 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising an anti-CD66a antibody or the antibody 4D1/C2 with successful completion of the deposit requirement, does not reasonably provide enablement for a pharmaceutical composition for negative regulation of angiogenesis or stopping tumor growth with any antibody to CD66a or any antibody or protein that inhibits the interaction between CD66a and any CD66a ligand is withdrawn in view of arguments.

11. The rejection of claims 1, 2-4, 6 under 35 U.S.C. 102(b) as being anticipated by Draberova et al (Folia Biologica 43:343, 1997, PTO 892 #5) is withdrawn in view of the amendments to the claims.

12. The rejection of claims 1, 2-4, 6 under 35 U.S.C. 102(e) as being anticipated by Blumberg (U.S. Patent publication US 2002/0028203, with priority to 4/15/98) is withdrawn in view of the amendments to the claims.

Response to Arguments

13. The rejection of newly amended claims 1-2, 6, 8 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 9/18/03 has been carefully considered but is deemed not to be persuasive. The response states Applicants have requested a copy of the Certification of the Availability, but to date have not received it (see page 5 of response). In response to this argument, all assurances have not been met and as such the rejection stands.

14. The rejection of claims 1, 2, 6, and newly added claim 8 under 35 U.S.C. 102(b) as being anticipated by Drzeniek et al (Cancer Letters 56:173-79, 1991) as evidenced from the specification is maintained.

The response filed 9/18/03 has been carefully considered but is deemed not to be persuasive. The response states that the reference clearly stated that the discussed Mab 4D1/C2 preferentially binds the antigen of 85,000 and there was no binding to the 170,000 antigen and neither reference (Prall also included in this response) discloses teaches or suggest that the antibody is effective to inhibit or reduce formation of capillaries nor can it be inherent (see page 8-9 of response). In response to these arguments, The specification discloses that the 4D1/C2 antibody of Drzeniek et al is the 4D1/C2 antibody that was deposited and used in the specification. Therefore, the antibody binds the CD66a antigen and has all of the properties of the antibody and would inherently reduce angiogenesis and reduce formation of capillaries.

15. The rejection of claims 1, 2, 6, and newly added claim 8 under 35 U.S.C. 102(b) as being anticipated by Prall et al (The Journal of Histochemistry and Cytochemistry 44:35-41, 1996) is maintained.

The response filed 9/18/03 has been carefully considered but is deemed not to be persuasive. The response states that the reference clearly stated that the discussed Mab 4D1/C2 preferentially binds the antigen of 165,000 and there was no binding to the 170,000 antigen and neither reference (Drzeniek et al included in this response) discloses teaches or suggest that the antibody is effective to inhibit or reduce formation of capillaries nor can it be inherent (see page 8-9 of response). In response to these arguments, the specification discloses that the 4D1/C2 antibody of Drzeniek et al is the

4D1/C2 antibody that was deposited and used in the specification. Prall et al specifically teaches that the antibody was described previously and cites the Drzeniek et al, Cancer Letters reference. Therefore, the antibody binds the CD66a antigen and has all of the properties of the antibody and would inherently reduce angiogenesis and reduce formation of capillaries.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



LARRY R. HELMS, PH.D
PRIMARY EXAMINER